

PATENT COOPERATION TREATY

IFD

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

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| To: | | |
| WOLF, GREENFIELD & SACKS, P.C. Attn. Oyer, Timothy J. 600 Atlantic Avenue Federal Reserve Plaza Boston, Massachusetts 02210 ETATS-UNIS D'AMERIQUE | | |

REGISTERED MAIL

**INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE**
(PCT Article 17(3)(a) and Rule 40.1 and 40.2(e))

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| Applicant's or agent's file reference C1256.70004 | Date of mailing (day/month/year) 19/04/2010 |
| International application No. PCT/US2009/006596 | PAYMENT DUE within ONE MONTH from the above date of mailing |
| Applicant CLAROS DIAGNOSTICS, INC. | International filing date (day/month/year) 17/12/2009 |

1. This International Searching Authority
 - (i) considers that there are 3 (number of) inventions claimed in the international application covered by the claims indicated on an extra sheet:
 - (ii) therefore considers that **the international application does not comply with the requirements of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated on an extra sheet:
 - (iii) has carried out a partial international search (see Annex) will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

see extra sheet
 - (iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.
2. Consequently, the applicant is hereby **invited to pay**, within the time limit indicated above, the amount indicated below:

EUR 1.700,00 x 2 = EUR 3.400
Fee per additional invention number of additional inventions currency/total amount of additional fees
3. The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fee may be made under protest**, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive, where applicable, subject to the payment of a protest fee. Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of EUR 790,00 (currency/amount). Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. Claim(s) Nos. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

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Wolf, Greenfield & Sacks, P.C.

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| Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 | Authorized officer Nuria Carretero Botella <i>APR 27 2010</i> |
| Docketed <input checked="" type="checkbox"/> Already Docketed <input type="checkbox"/> Not Required <input type="checkbox"/> Initials 1st <i>Nur</i> 2nd <i>JMB</i> | |

Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

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| <p style="margin: 0;">International Application No</p> | <p style="margin: 0;">PCT/US2009/006596</p> |
|--|---|

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:

see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|--|
| X | US 6 331 439 B1 (CHERUKURI SATYAM CHOUDARY [US] ET AL) 18 December 2001 (2001-12-18) | 1,5-8, 10, 14-17, 21,24, 37,41, 50,52-58 |
| Y | column 1, line 9 - column 1, line 15 column 2, line 42 - column 3, line 43; figures 2,2A,3-6 column 7, line 19 - column 8, line 68 | 2,11-13, 18-20, 22-23, 26-27, 38-40, 42,54-58 |
| X | WO 2008/123112 A1 (TOSHIBA KK [JP]; HONGO SADATO [JP]; KOKUBO TAKAHIRO [JP]; HORIUCHI HID) 16 October 2008 (2008-10-16) | 1,5-8, 10, 14-16, 21, 37-42, 50,52-58 |
| Y | figures 1,2,5-9,16-22,24-26,30-35 | 11-13, 22, 26-27,42 |
| X,P | -& EP 2 071 026 A1 (TOSHIBA KK [JP]) 17 June 2009 (2009-06-17) paragraphs [0011], [0015], [0016], [0021], [0209]; figures 1,2,5-9,16-22,24-26,30-35 | 1,5-6,8, 10,21, 39-42,52 |
| | ----- -/- | |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

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| International Application No PCT/US2009/006596 |
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|---|
| X | US 2008/248590 A1 (GULLIKSEN ANJA [NO] ET AL) 9 October 2008 (2008-10-09) paragraph [0058]; claims 1,7-9,12,14-18 | 53 |
| Y | ----- WO 2008/118098 A1 (AGENCY SCIENCE TECH & RES [SG]; LEVENT YOBAS [SG]; CHEOW LIH FENG [SG]) 2 October 2008 (2008-10-02) paragraphs [0015], [0081]; figures 17-19,21 | 11-13, 18-20, 22-23, 39-40, 54-58 |
| Y | ----- US 2003/124623 A1 (YAGER PAUL [US] ET AL) 3 July 2003 (2003-07-03) paragraphs [0087] - [0091]; claims 1-3,7-14 | 18-20, 22-23,39 |
| Y | ----- US 2007/048189 A1 (COX DAVID M [US] ET AL) 1 March 2007 (2007-03-01) figures 1,2 | 2,26-27, 55-56 |
| Y | ----- EP 1 946 830 A1 (KONICA MINOLTA MED & GRAPHIC [JP]) 23 July 2008 (2008-07-23) paragraph [0079] - paragraphs [0084], [0170]; figure 3 | 11-12, 18-20 |

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 5, 10-23, 38, 41, 52(completely); 6-8, 24, 26-27, 37, 39-40, 42, 50(partially)

fluidic device with a reagent or a chemical stored in at least one channel of said device

1.1. claims: 2, 25-27

fluidic device with covers and sealed inlets and outlets

1.2. claims: 53-58

method of filling a fluidic device comprising a substrate with surfaces comprising interconnected first and second microchannels further comprising a cover over a first surface of the substrate thus enclosing first and/or second microchannels, the method comprising the step of filling at least a portion of two first microfluidic channel segments with a fluid without filling a second microfluidic channel segment positioned between said two first microfluidic channel segments

2. claims: 3, 9, 28-36(completely); 6-8, 24, 26-27, 37, 39-40, 42, 50(partially)

fluidic device with microfluidic channels having cross-sections with a convex portion and a concave portion

3. claims: 4, 9, 43-49, 51(completely); 6-8, 24, 26-27, 37, 39-40, 42, 50(partially)

fluidic device made of a substrate with several surfaces and wherein microfluidic channels have no more than 5% of the perimeter of a cross-section perpendicular to the surfaces of the substrate

Please note that all inventions mentioned under item 1, although not necessarily linked by a common inventive concept, could be searched without effort justifying an additional fee.

This Authority considers that the application does not meet the requirements of unity of invention and that there are 3 inventions covered by the claims indicated as follows:

Group 1: claims 1, 2, 5, 10-27, 38, 41, 52, 53-58 and claims 6-8, 37, 39, 40, 42, 50 (inasmuch as they are referring back to claims 1 and/or 2);

Group 2: claims 3, 28-36 and, inasmuch as they are referring back to

claim 1, claims 6-8, 37, 39, 40, 42, 50 (inasmuch as they are referring back to claims 1 and/or 2);

Group 3: claims 4, 9, 43-49, 51 and claims 6-8, 37, 39-40, 42, 50 (inasmuch as they are referring back to claims 1 and/or 2).

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The common part of groups 1, 2 and 3 is a fluidic device comprising: an article comprising first and second surfaces; a first microfluidic channel segment formed in the first surface of the article; a second microfluidic channel segment formed in the second surface of the article; an intervening channel passing through the article from the first surface to the second surface and connecting the first and second microfluidic channel segments. Said common part is known from US-B-6,331,439 (D1).

D1 discloses a fluidic device comprising (see figure 3):

- an article comprising first and second surfaces (cf "center distribution plate" 310);
- a first microfluidic channel segment (cf microchannel 212) formed in the first surface of the article;
- a second microfluidic channel segment (cf microchannel 216) formed in the second surface of the article;
- an intervening channel (cf channel 214) passing through the article from the first surface to the second surface and connecting the first and second microfluidic channel segments.

The different groups of inventions address different problems with different special technical features:

Group 1 is addressing problems related to the storage of reagents in a microfluidic device. Its special technical features are storing a reagent in a portion of a channel and/or providing a cover for both surfaces of the article and sealing inlet and outlet of the first and second microchannels.

Group 2 is addressing problems relating to easiness of the fabrication of fluidic devices (cf page 5, line 32, to page 6, line 3). The special technical features of group 2 are a first portion of the article adjacent the cover that is convex and a second portion continuous with the first portion that is linear or concave.

Group 3 is also addressing problems relating to the fabrication of fluidic devices. Here the special technical features are a first and a second microfluidic channel wherein no more than 5% of the perimeter of a cross section of the first microfluidic channel segment, resp. second channel segment, is perpendicular to the first surface, resp. to the second surface.

Hence, group 1, on the one hand, and groups 2 and 3, on the other hand, are addressing different problems with different special technical features. Furthermore, although group 2 and group 3 are addressing related problems, the special technical features with whom they are addressing said problems are different and cannot be considered as equivalent. In conclusion the groups of inventions have no common special technical features. The requirements of Rule 13.2 PCT are not fulfilled.

Furthermore, the subject-matter of claim 1 is not novel (Art. 33(2) PCT) and not inventive (Art. 33(3) PCT) over D1. D1, besides disclosing the features common to the subject-matter of claims 1, 2, 3 and 4, also discloses a reagent for chemical and/or biological reaction stored in at least a portion of a channel of the fluidic device (cf e.g. reservoir 200 in figure 3). The feature of claim 1 according to which the reagent is stored "for greater than one day prior to first use of the fluidic device" relates to the use of said device and cannot further define the subject-matter of claim 1, nor can it help to distinguish the subject-matter of claim 1 from the device of D1 (Art. 6 PCT, clarity). In conclusion, the subject-matter of claim 1 is not novel (Art. 33(2) PCT) over D1 and thus not inventive (Art. 33(3) PCT). As the subject-matter of claim 1, i.e. of group 1 is lacking an inventive step, there can be no common inventive concept shared by the different groups 1, 2 and 3 as defined above. In other words the groups of potential inventions are not linked by a single general inventive concept as required by Rule 13.1 PCT.

Patent Family Annex

Information on patent family members

International Application No

PCT/US2009/006596

| Patent document cited in search report | Publication date | Patent family member(s) | | | Publication date |
|--|------------------|-------------------------|----------------|--|--|
| US 6331439 | B1 | 18-12-2001 | | | NONE |
| WO 2008123112 | A1 | 16-10-2008 | | | NONE |
| EP 2071026 | A1 | 17-06-2009 | CN JP US | 101541962 A 2008263959 A 2009023201 A1 | 23-09-2009 06-11-2008 22-01-2009 |
| US 2008248590 | A1 | 09-10-2008 | EP WO | 1838869 A1 2006056787 A1 | 03-10-2007 01-06-2006 |
| WO 2008118098 | A1 | 02-10-2008 | NONE | | |
| US 2003124623 | A1 | 03-07-2003 | NONE | | |
| US 2007048189 | A1 | 01-03-2007 | WO | 2007024417 A2 | 01-03-2007 |
| EP 1946830 | A1 | 23-07-2008 | WO US | 2007052471 A1 2009155927 A1 | 10-05-2007 18-06-2009 |